

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 10-74 are now pending, and claims 29-74 are withdrawn. In addition, the Office Action states that claims 23 and 27-28 are withdrawn from examination due to including non-elected species. Accordingly, claims 10-22 and 24-26 are under consideration.

I. Claim Rejections – 35 U.S.C. § 103

Claims 10-22 and 24-26 remain rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,145,684 to Liversidge *et al.* (“Liversidge”) in view of Lacy *et al.*, DRUG INFORMATION HANDBOOK, pp. 95-96 (Lexi-Comp, Inc. 1993) (“DIH”) for reasons stated in the previous Office Action. The previous Office Action states that Liversidge teaches each and every element of the claims, except beclomethasone dipropionate. DIH is cited to remedy this deficiency. According to the previous Office Action,

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general formulations of Liversidge on formulations containing active agents including corticosteroids, to have looked in the art for other specific species of corticosteroids suitable for formation of compositions, as disclosed in Drug Information Handbook, with reasonable expectations of successfully preparing formulations comprising different active agents for treating different disorders.

Applicants respectfully traverse this ground of rejection.

A. The prior art does not teach or suggest a nanoparticulate composition of beclomethasone dipropionate of the claimed invention because there is no motivation to combine Liversidge and DIH.

The claimed invention is directed to nanoparticulate compositions comprising beclomethasone dipropionate particles having an average particle size of less than about 1000 nm and at least one surface modifier. Liversidge generally relates to nanoparticles of a crystalline

drug substance with a surface modifier absorbed on the surface thereof. In that regard, Liversidge discloses a lengthy list of classes of drugs substances, such as corticosteroids, and examples of some particular drug substances, such as Steroid A. However, Liversidge makes no mention of beclomethasone dipropionate.

DIH does not remedy the deficiencies of Liversidge because there is no motivation to combine the references. Specifically, there is no motivation for a skilled artisan to select beclomethasone dipropionate from the large numbers drugs falling into the numerous drug categories listed in Liversidge. Furthermore, there is no motivation for a skilled artisan to select beclomethasone dipropionate from the large number of corticosteroid drugs. The Examiner's assertion in the current Office Action that "beclomethosone dipropionate is indeed widely used and well known corticosteroid" (Office Action at 4) does not satisfy the requirement for a motivation to combine.

B. There is no expectation of success in selecting beclomethasone dipropionate and applying the teachings of Liversidge in the making of a nanoparticulate composition.

Liversidge teaches that "not every combination of surface modifier and drug substance provides the desired results [of a stable nanoparticulate composition]." Liversidge, col. 7, lines 21-23. Thus, if one skilled in the art were to select beclomethosone dipropionate from the large number of drugs falling into the categories recited in Liversidge, he would have no expectation of success in making a stable nanoparticulate composition, according to the teaching of Liversidge. This is due in part to the requirement that the surface modifier adsorb to the surface of the drug substance. Indeed, Liversidge teaches that "[t]he surface modifier is adsorbed on the surface of the drug substance in an amount sufficient to maintain an effective average particle size of less than about 400 nm." Liversidge, col. 5, lines 13-15. The adsorption of the surface stabilizer to the drug substance is essential in the formation of stable nanoparticles. Thus, one of skill in the art would not have known *a priori* whether or not a surface stabilizer would adsorb to beclomethosone dipropionate particles and therefore, would not have known whether the stable beclomethosone dipropionate nanoparticles could be formed.

Thus, one of skill in the art would have had no expectation of success in selecting beclomethasone dipropionate and employing the teachings of Liversidge. *See* MPEP § 2143.02. Accordingly, Liversidge and DIH fail to render the claimed invention obvious.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

II. Obviousness-Type Double Patenting

A. U.S. Patent No. 6,264,922

Claims 10-22 and 24-26 remain rejected “under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-16 of U.S. Patent No. 6,264,922 B1” (Office Action at page 3).

As confirmed by the Examiner in a telephone interview on June 20, 2006, this rejection has been rendered moot by the filing of a Terminal Disclaimer for U.S. Patent No. 6,264,922 on December 30, 2005.

B. U.S. Patent No. 6,811,767

Claims 10-22 and 24-26 stand “rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-13 of U.S. Patent No. 6,811,767 B1.” Office Action at 5.

While Applicants respectfully disagree with the Examiner’s assertion for at least the reasons already of record, filed herewith for the sole purpose of advancing the prosecution of this case is a Terminal Disclaimer for U.S. Patent No. 6,811,767.

C. U.S. Patent No. 5,747,001

Claims 10-22 and 24-26 stand “rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,747,001” (Office Action at page 3).

As confirmed by the Examiner in a telephone interview on June 20, 2006, this rejection has been rendered moot by the filing of a Terminal Disclaimer for U.S. Patent No. 6,264,922 on December 30, 2005.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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